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1. PURPOSE

- 1.1. This **policy** establishes the process for Human Subjects Office (HSO) Staff to triage information submitted to the University of Georgia Institutional Review Board (UGA IRB).

2. POLICY

- 2.1. The HSO carries out these procedures.

3. PROCEDURES: Human Subjects Office

- 3.1. The process begins when the IRB receives information or communication and ends when the appropriate action for the information has been determined.
- 3.2. If the information is a request for an approval or determination (approval of new research, response to modifications required to secure approval, **continuing review** of research, **modification** to previously approved research, request for study closure, or a determination if an activity is not human research or if meets the Developmental Review criteria) , the *Policy and Procedures: Pre-Review* must be followed.
- 3.3. If the information is a prior notification of an **emergency use of a test article** in a life-threatening situation, the *Policy and Procedures: Emergency Use of a Test Article Review* must be followed.
- 3.4. If the information is a five-day notification after an emergency use of a test article in a life-threatening situation, the *Policy and Procedures: Emergency Use of a Test Article Review* must be followed.
- 3.5. If the information is a request from the **Investigator** to continue subjects in a study whose IRB approval has **expired**, the *Policy and Procedures: Expiration of IRB Approval* must be followed.
- 3.6. If the information is a question, concern, or complaint:
- 3.6.1. The HSO Staff documents the nature of the question, concern, or complaint and the name and contact information of the person contacting the IRB (unless the person would like to remain anonymous).
- 3.6.2. The HSO Staff will respond to any questions or concerns that are basic or general in nature. For questions or concerns that are complicated or cannot be readily responded to, the HSO Staff will let the person know that additional information will be obtained and communicated to him/her by phone or email as soon as this becomes available. The HSO Director, IRB Chair, and/or Office of Research Compliance Director must be consulted to identify the best course of action for the received information.
- 3.6.3. The HSO Staff must follow the *Office of Research Compliance (ORC) Policy and Procedures: Responding to Allegations of Research Non-Compliance*.

4. MATERIALS

- 4.1. None



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5. REFERENCES

- 5.1. Policy and Procedures: Pre-Review
- 5.2. Policy and Procedures: Emergency Use of a Test Article Review
- 5.3. Policy and Procedures: Expiration of IRB Approval
- 5.4. ORC Policy and Procedures: Responding to Allegations of Research Non-Compliance